

**STATEMENT OF
THE HONORABLE MIKE BILIRAKIS
HOUSE COMMITTEE ON COMMERCE
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT**

APRIL 30, 1997

**HEARING ON MEDICAL DEVICES:
TECHNOLOGICAL INNOVATION AND
PATIENT/PROVIDER PERSPECTIVES**

**I AM PLEASED TO OPEN THIS HEARING ON MEDICAL
DEVICE INNOVATION. IN WHAT I EXPECT WILL BE A
FASCINATING MORNING, WE WILL LEARN ABOUT
TECHNOLOGICAL ADVANCES IN THE FIELD OF MEDICAL
DEVICES FROM THE PERSPECTIVE OF THE FDA, AS WELL AS
FROM PATIENTS AND PROVIDERS.**

**AT THE OUTSET, I WANT TO STRESS THAT THE PURPOSE
OF THIS HEARING IS INFORMATIONAL. RATHER THAN FOCUS
TODAY ON ISSUES RELATING TO FDA REFORM, I HOPE WE WILL
TAKE THIS OPPORTUNITY TO LEARN MORE ABOUT THE MANY
ADVANCES THAT HAVE TAKEN PLACE IN THE FIELD OF
MEDICAL DEVICES.**

SINCE THIS COMMITTEE WILL HOLD ADDITIONAL HEARINGS ON FDA REFORM IN THE COMING WEEKS, TODAY'S HEARING IS INTENDED TO HELP US ENSURE THAT OUR REFORM EFFORTS BENEFIT FROM A FULL UNDERSTANDING OF THE TREMENDOUS VALUE OF MEDICAL DEVICES TO PHYSICIANS AND PATIENTS.

AS WE WILL HEAR FROM FDA'S LEAD DEPUTY COMMISSIONER, DR. MICHAEL FRIEDMAN, MEDICAL DEVICES HAVE IMPROVED DRAMATICALLY SINCE THE ORIGINAL FEDERAL FOOD, DRUG AND COSMETIC ACT WAS PASSED IN 1938. AT THAT TIME, MEDICAL DEVICES WERE RELATIVELY SIMPLE INSTRUMENTS, WITH TYPICAL DEVICES CONSISTING OF LITTLE MORE THAN STETHOSCOPES AND SCALPELS.

FOLLOWING WORLD WAR II AND THE RESEARCH BORN OF THE SPACE AGE AND THE COLD WAR, THE NUMBER AND CAPABILITY OF MEDICAL DEVICES GREATLY INCREASED.

TODAY, ADVANCES IN MEDICAL DEVICE TECHNOLOGY, AND THE RESULTING BENEFITS REALIZED BY THE AMERICAN PEOPLE, CAN ONLY BE DESCRIBED AS TRULY REVOLUTIONARY.

THIS MORNING, WE WILL LEARN ABOUT SOME OF THESE NEW LIFE-SAVING AND -SUSTAINING DEVICES, INCLUDING:

- **HEART LASERS THAT ARE USED IN TREATING CORONARY DISEASE IN PATIENTS WITH NO OTHER TREATMENT OPTIONS,**
- **COMPUTER-AIDED DIGITAL MAMMOGRAPHY THAT PROVIDES A RADIOLOGIST WITH A CRITICAL “SECOND OPINION” IN BREAST CANCER CASES,**
- **BIOENGINEERED REPLACEMENT SKIN FOR VICTIMS OF SEVERE BURNS,**
- **BRAIN IMPLANTS THAT GREATLY ASSIST VICTIMS OF PARKINSON’S AND RELATED TREMOR DISEASES, AND**
- **IMPLANTABLE CARDIAC DEFIBRILLATORS THAT HAVE PROVEN CLEARLY SUPERIOR TO DRUG THERAPY IN PATIENTS WITH FATAL HEART ABNORMALITIES.**

**OF COURSE, THESE ARE JUST A FEW OF THE
BREAKTHROUGH MEDICAL DEVICES THAT HAVE RESULTED
FROM THE CURRENT REVOLUTION IN MICROELECTRONICS,
ORGAN DISEASE TREATMENT, WOMEN'S HEALTH, AND
MEDICAL DIAGNOSES, AMONG OTHER ADVANCES.**

**THAT IS WHY I BELIEVE IT IS IMPORTANT FOR THE
MEMBERS OF THIS COMMITTEE TO HAVE THE OPPORTUNITY
TO SEE, TOUCH, AND LEARN ABOUT A REPRESENTATIVE
SAMPLE OF THE INNOVATIVE MEDICAL DEVICES SERVING
AMERICA'S PATIENTS.**

**I LOOK FORWARD TO THE TESTIMONY OF OUR WITNESSES
TODAY AND WANT TO EXTEND OUR SINCERE APPRECIATION
TO EACH OF YOU FOR YOUR TIME AND ASSISTANCE IN HELPING
TO EDUCATE US ABOUT THE USE, BENEFITS, AND IMPORTANCE
OF MEDICAL DEVICES.**